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No. 84-1737

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

UNITED STATES OF AMERICA,
Petitioner,

v.

THE AMERICAN COLLEGE OF PHYSICIANS,
Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

RESPONDENT'S MEMORANDUM IN OPPOSITION TO MOTION OF AMERICAN BUSINESS PRESS FOR LEAVE TO FILE AMICUS BRIEF

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Respondent American College of Physicians ("the College") opposes the motion of American Business Press ("ABP") for leave to file an amicus brief in support of the petition. The College declined to consent to the filing of ABP's brief because counsel for ABP refused to provide any information about the contents of their proposed brief or to make any commitment to try to file in advance of the deadline for the College's opposition to the petition, and past experience with ABP in this case indicated a likelihood that the ABP brief would make unsupported, inaccurate statements which could mislead the Court if there were no response. Such apprehensions were well-founded, for much of ABP's brief is inaccurate, distorted,

irrelevant or not in compliance with this Court's rules. Without answering in detail, we note several examples.

1. ABP proffers purportedly representative copies of advertisements for a prescription drug, including one from the January 1985 *Annals*, as illustrating "what this case is all about" (ABP Br. 4-5). However, the copies reflect virtually none of the important content of the advertisements, even though "what this case is all about" is whether there is a substantial relationship between such advertisements (in the 1975 *Annals*) and the exempt educational purpose of the College. Thus, like the government, ABP has made a misleading presentation of the advertisements. What has been assertedly "reproduced" is but one page of an eight-page advertisement introducing a new prescription drug, which contains an abundance of detailed technical information that is important for the physician-readers of *Annals* to know (pp. I-17 to I-24).[1] Most such information in the two full columns of copy on the page excerpted by ABP (a legible copy of which is appended hereto as Appendix A) has been totally obscured, eliminated or otherwise omitted in the reproduction process.[2]

2. ABP asserts broadly that the primary purpose of Section 513 is to protect non-exempt organizations from "unfair competition" by exempt organizations (ABP Br. 4-7). In fact, Congress chose to address competition only insofar as it came from *unrelated* trade or business activities of exempt organizations, which it defined as those not

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[1] We are lodging with the Clerk a copy of the January 1985 issue of *Annals*.

[2] The reproductions of the advertisements in ABP's brief appear to violate Rule 33.1 of this Court concerning legibility.

"substantially related" to the purposes underlying the organization's exemption.

3. ABP implies that the "tax exempt" organizations identified as its competitors are comparable to respondent (ABP Br. 2-3), but we understand that all of them are exempt under Section 501(c)(6) of the Internal Revenue Code, and none under Section 501(c)(3), which is the only type of exempt organization involved in this case.[3]

4. ABP asserts that the Claims Court, in a "considered opinion," correctly "enforced the IRS Regulations and the Act of Congress* * *" (ABP Br. 3, 14).[4] However, ABP argued in the Court of Appeals that the Claims Court's factually oriented approach was contrary to the per se approach advocated by ABP. Moreover, in its effort to intervene in the *AMA* case (ABP Br. 16), ABP had the following to say about the instant case:

> In the *ACP* proceeding, the Government and ACP agreed that a factual inquiry into the advertising

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[3] ABP cites data concerning the total number of various categories of exempt organizations (ABP Br. 15 n.6), but fails to provide any data as to the relatively small number of such organizations that publish magazines containing advertisements from which they derive significant income, or, more importantly, the number of such organizations that could plausibly assert that such advertising contributes importantly to their exempt purposes.

[4] ABP asserts that the court of appeals, by contrast, made "no mention whatsoever" of the regulation assertedly "validated and given the force of law by Congress in 1969" (ABP Br. 3, 14), but in fact the court repeatedly analyzed and construed the regulation (Pet. App. 6a, 9a, 10a, 12a, 19a-20a). While the court did not discuss Example 7 in the regulations, on which ABP relies, that example is on its face applicable only to a Section 501(c)(6) organization, and in any event that example was not discussed or "validated" by Congress (or the committees), particularly with reference to its possible application to a Section 501(c)(3) organization such as the College.

> activity of the ACP and its relationship to exempt functions was required. In ABP's judgment, the Government never should have proceeded to a trial of "the relatedness" of ACP's advertising business to its tax-exempt purpose without asserting available legal defenses which could have been raised by summary judgment.[5]

ABP further referred to *the government's* "case-by-case approach" in this area.[6] Thus, ABP concurs with the College's characterization of the instant case, which makes it not a suitable vehicle for addressing the question the government now seeks to present.

5. ABP makes the unsupported assertion that the taxpayer in one of the three pending district court cases involving (c)(6) organizations noted in the petition (Pet. 25-26 n.3) has "indicated" that it plans to dismiss its district court action, in what ABP surmises would be "the first step" in moving its claims to the Federal Circuit (ABP Br. 15-16). However, ABP misdescribes the situation in that case[7] and fails to mention that the taxpayer in another of those cases recently amended its complaint to

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[5] Memorandum of Points & Authorities in Support of the Motion of American Business Press for Leave to Intervene, *American Medical Ass'n* v. *United States*, No. 82 C 7213 at 19 (N.D. Ill.).

[6] *Id.* at 20.

[7] We are advised that AMA has merely indicated that it had referred to the possibility of a dismissal *without prejudice*, which it could obtain at this stage of that case only in the event that the government consented or the court granted such a motion over the government's opposition (*see* Fed. R. Civ. P. 41(a)), both of which events are problematical at best. ABP also omitted to mention that the government opposed its motion to intervene in *AMA*, rejecting ABP's assertion of competitive impact in terms applicable here:

> the possibility that if the AMA wins the suit it might lower its advertising rates and divert income away from the members of

make a substantial claim that it is not likely to be dismissed in order that it can forum shop, as ABP implies.[8]

Accordingly, the motion of ABP should be denied and its brief disregarded.

Respectfully submitted,

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the ABP is, the Government submits, not an immediate, but rather a remote consequence of an adverse decision. Other than this potential economic handicap, a decision either in favor of or against the AMA can have no direct immediate effect on the ABP.

Memorandum of the United States of America Opposing Intervention By the American Business Press, *American Medical Ass'n* v. *United States*, No. 82 C 7213 at 4 (N.D. Ill.).

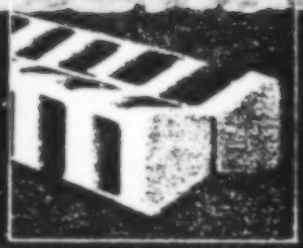
[8] We are advised that the plaintiff in *American Academy of Family Physicians* v. *United States*, Civ. No. 84-0170-CV-W-4 (W.D. Mo.), has amended the complaint to assert a claim for refund exceeding $2 million, so that there is no serious prospect that the plaintiff would suffer a dismissal in order to litigate in the Claims Court.

APPENDIX

NEW 1 tab qd

MAXZIDE™

Triamterene **75 mg**/Hydrochlorothiazide **50 mg**/Lederle



– FOR PATIENTS ON HYDROCHLOROTHIAZIDE WHO DEVELOP HYPOKALEMIA
– FOR NEWLY DIAGNOSED PATIENTS IN WHOM THE DEVELOPMENT OF HYPOKALEMIA CANNOT BE RISKED
– FOR PATIENTS TRANSFERRED FROM DYAZIDE

BRIEF SUMMARY
Please see package insert for full prescribing information.

INDICATIONS AND USAGE: MAXZIDE is indicated for the treatment of hypertension or edema in patients who develop hypokalemia on hydrochlorothiazide alone. It is also indicated for those patients who require a thiazide diuretic and in whom the development of hypokalemia cannot be risked (e.g., patients on digitalis preparations or with a history of cardiac arrhythmias, etc.). **This fixed combination drug is not indicated for the initial therapy of edema or hypertension except in individuals in whom the development of hypokalemia cannot be risked.** MAXZIDE may be used alone or in combination with other antihypertensive drugs such as beta-blockers. Since MAXZIDE may enhance the actions of these drugs, dosage adjustments may be necessary. Usage in Pregnancy. The routine use of diuretics in an otherwise healthy woman is inappropriate and exposes mother and fetus to unnecessary hazards. Diuretics do not prevent development of toxemia in pregnancy, and there is no satisfactory evidence that they are useful in the treatment of developed toxemia.

CONTRAINDICATIONS: Hyperkalemia. MAXZIDE should not be used in the presence of elevated serum potassium levels (greater than 5.5 mEq/liter). If hyperkalemia develops, this drug should be discontinued and a thiazide alone should be substituted. Concomitant use with other potassium conserving agents such as spironolactone, amiloride HCl or other formulations containing triamterene. Concomitant potassium supplementation in the form of medication, potassium-containing salt substitute or potassium-enriched diets should also not be used. Contraindicated in patients with anuria, acute and chronic renal insufficiency or significant renal impairment. Hypersensitivity to either component separately or other sulfonamide-derived drugs.

WARNINGS: Hyperkalemia

> Abnormal elevation of serum potassium levels (greater than or equal to 5.5 mEq/liter) can occur with all potassium conserving agents including MAXZIDE. Hyperkalemia is more likely to occur in patients with renal impairment, diabetes (even without evidence of renal impairment), or elderly or severely ill patients. Since uncorrected hyperkalemia may be fatal, serum potassium levels must be monitored at frequent intervals especially in patients first receiving MAXZIDE, when dosages are changed, or with any illness that may influence renal function.

If hyperkalemia is suspected, (warning signs include paresthesias, muscular weakness, fatigue, flaccid paralysis of the extremities, bradycardia and shock) an electrocardiogram (ECG) should be obtained. Monitor serum potassium levels because mild hyperkalemia may not be associated with ECG changes. If hyperkalemia is present, MAXZIDE should be discontinued immediately and a thiazide alone should be substituted. If the serum potassium level exceeds 6.5 mEq/liter, more vigorous therapy is required. The clinical situation dictates the procedures to be employed. These include the intravenous administration of calcium chloride, dextrose and sodium bicarbonate solution and the oral or parenteral administration of glucose with a rapid acting insulin preparation. Cation exchange resins such as sodium polystyrene sulfonate may be given orally or rectally. Administration of hyperkalemia may require dialysis. The development of hyperkalemia is assisted with potassium-sparing diuretics is accentuated in the presence of renal impairment (see CONTRAINDICATIONS). Patients with mild renal dysfunction or impairment should not receive this drug without frequent and continued monitoring of serum electrolytes. Cumulative drug effects may be observed in patients with impaired renal function. The renal clearance of hydrochlorothiazide, the pharmacologically active metabolite of triamterene, and the sulfate ester of hydroxytriamterene have been shown to be reduced and the plasma levels increased following MAXZIDE administration to elderly patients and patients with impaired renal function. Hyperkalemia has been reported in diabetic patients with the use of potassium conserving agents even in the absence of apparent renal impairment. Avoid MAXZIDE in diabetic patients. If it is employed, serum electrolytes must be frequently monitored. Metabolic or Respiratory Acidosis. Potassium conserving therapy should also be avoided in severely ill patients in whom respiratory or metabolic acidosis may occur, since acidosis may be associated with rapid elevations in serum potassium levels. If MAXZIDE™ triamterene 75mg/hydrochlorothiazide 50mg is employed, frequent evaluations of acid-base balance and serum electrolytes are necessary.

PRECAUTIONS: Electrolyte Imbalance and BUN Increases. Patients receiving MAXZIDE should be carefully monitored for fluid or electrolyte imbalances, i.e., hyponatremia, hypochloremic alkalosis, hypokalemia and hypomagnesemia. Serum and urine electrolyte determinations should be frequently performed and are especially important when the patient is vomiting or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance include: dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia and gastrointestinal disturbances such as nausea and vomiting.

Any chloride deficit during thiazide therapy is generally mild and usually does not require any specific treatment except under extraordinary circumstances (as in liver disease or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt, except in rare instances when the hyponatremia is life threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hypokalemia may develop with thiazide therapy, especially with brisk diuresis, when severe cirrhosis is present, or during concomitant use of corticosteroids, ACTH, amphotericin B or after prolonged thiazide therapy. However, hypokalemia of this type is usually prevented by the triamterene component of MAXZIDE.

Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia can sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability).

MAXZIDE may produce an elevated blood urea nitrogen level (BUN), creatinine level or both. This is probably not the result of renal toxicity but is secondary to a reversible reduction of the glomerular filtration rate or a depletion of the intravascular fluid volume. Periodic BUN and creatinine determinations should be made especially in elderly patients, patients with suspected or confirmed hepatic disease or renal insufficiencies. If azotemia increases, MAXZIDE should be discontinued.

Hepatic Coma. MAXZIDE should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Renal Stones. Triamterene has been reported in renal stones in association with other calculus components. MAXZIDE should be used with caution in patients with histories of renal lithiasis. Folic Acid Deficiency. Triamterene is a weak folic acid antagonist and may contribute to the appearance of megaloblastosis in instances where folic acid stores are decreased. In such patients, periodic blood evaluations are recommended. Hyperuricemia. Hyperuricemia may occur or acute gout may be precipitated in certain patients receiving thiazide therapy. Metabolic and Endocrine Effects. The thiazides may decrease serum PBI levels without signs of thyroid disturbance.

Calcium excretion is decreased by thiazides. Pathological changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a few patients on prolonged thiazide therapy. The common complications of hyperparathyroidism such as renal lithiasis, bone resorption, and peptic ulceration have not been seen. Thiazides should be discontinued before carrying out tests for parathyroid function.

Insulin requirements in diabetic patients may be increased, decreased or unchanged. Latent diabetes mellitus may become manifest during thiazide administration. Hypersensitivity. Sensitivity reactions to thiazides may occur in patients with or without a history of allergy or bronchial asthma.

Possible exacerbation or activation of systemic lupus erythematosus by thiazides has been reported. Drug Interactions. Thiazides may add to or potentiate the action of other antihypertensive drugs.

The thiazides may decrease arterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use. Thiazides have also been shown to increase responsiveness to tubocurarine.

Lithium, when given with diuretics, reduces renal clearance and increases the risk of lithium toxicity. Refer to the package insert on lithium before use of such concomitant therapy.

Acute renal failure has been reported in a few patients receiving indomethacin and other formulations containing triamterene and hydrochlorothiazide. Caution is therefore advised when administering nonsteroidal anti-inflammatory agents with MAXZIDE.

Drug Laboratory Test Interactions. Triamterene and quinidine have similar fluorescence spectra. Thus MAXZIDE may interfere with the measurement of quinidine.

Pregnancy Category C. The safe use of MAXZIDE in pregnancy has not been established. Animal reproduction studies have not been conducted with MAXZIDE (triamterene 75mg/hydrochlorothiazide 50mg). It is also not known if MAXZIDE can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. MAXZIDE crosses the placental barrier and appears in cord blood. The use of thiazides in pregnant women requires that the anticipated benefit be weighed against possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, pancreatitis, and possibly other adverse reactions which have occurred in the adult. MAXZIDE should be given to a pregnant woman only if clearly needed.

Nursing Mothers. Thiazides appear in breast milk. If the use of MAXZIDE is deemed essential, the patient should stop nursing. Pediatric Use. The safety and effectiveness of MAXZIDE in children has not been established.

ADVERSE REACTIONS: Side effects observed in association with the use of MAXZIDE include drowsiness and fatigue, insomnia, muscle cramps and weakness, headache, nausea, appetite disturbance, vomiting, diarrhea, constipation, dizziness, decreased sexual performance, shortness of breath and chest pain, dry mouth, depression and anxiety. These adverse reactions are common to other triamterene and hydrochlorothiazide containing products. Other adverse reactions include:

Hydrochlorothiazide

Gastrointestinal: anorexia, gastric irritation, cramping, jaundice (intrahepatic cholestatic jaundice), pancreatitis, sialadenitis. Central Nervous System: vertigo, paresthesias, xanthopsia. Hematologic: leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia, hemolytic anemia, megaloblastosis. Cardiovascular: orthostatic hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Hypersensitivity: anaphylaxis, purpura, photosensitivity, rash, urticaria, necrotizing angiitis (vasculitis, cutaneous vasculitis), fever, respiratory distress including pneumonitis. Other: hyperglycemia, glycosuria, hyperuricemia, restlessness, transient blurred vision.

Triamterene

Hypersensitivity: anaphylaxis, photosensitivity and rash. Other: Triamterene has been reported in renal stones in association with other calculus materials. Triamterene has been associated with blood dyscrasias. Whenever adverse reactions are moderate to severe, therapy should be reduced or withdrawn.

DOSAGE AND ADMINISTRATION: The recommended dosage of MAXZIDE is one tablet daily with appropriate monitoring of serum potassium levels (see WARNINGS). Patients receiving 50 mg of hydrochlorothiazide who become hypokalemic may be transferred to MAXZIDE directly. In patients requiring 50 mg of hydrochlorothiazide in whom hypokalemia cannot be risked, therapy may be initiated with MAXZIDE. There is no clinical experience with doses exceeding one tablet daily.

Normotensive patients may show their positions already taking equivalent combinations of triamterene and hydrochlorothiazide (totaling 50-100 mg of hydrochlorothiazide and 100-200 mg of triamterene) may be safely changed to one MAXZIDE™ (triamterene 75mg/hydrochlorothiazide 50mg) tablet per day. These patients should be observed closely for a few weeks after the transfer.

Lederle

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